IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, AND NOVARTIS PHARMA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	**CIVIL ACTION NO. 1:14-cv-111** **(Judge Keeley)**

REPORT OF PARTIES' RULE 26(f) MEETING AND PROPOSED DISCOVERY PLAN

Pursuant to Fed. R. Civ. P. 16 and 26(f), Local Rule 16.01(b) and (c), and the Court's February 4th order (D.I. 40), the parties' counsel met by telephone on February 12, 2015. Shirley Cantin, Michael Horrell, and Jim Companion participated on behalf of plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively "Novartis"). Nicole Stafford, Sami Sedghani, Eric Arnell, and Jamie O'Brien participated on behalf of defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan"). Additional written communications followed. The parties discussed all matters required under Fed. R. Civ. P. 16 and 26(f), Local Rule 16.01(b) and (c).

1. **Pre-Discovery Disclosures**: The Court has established a deadline whereby the parties will exchange by March 12, 2015, the information required by Fed. R. Civ. P. 26(a)(1) and Local Rule 26.01(a).

2. **Discovery Scope**:

   (a) [**Novartis's Position:** The issues in this case include infringement/non-infringement and validity/invalidity of the patents-in-suit. The patents-in-suit have already been litigated close to trial in Delaware in *Novartis Pharm. Corp., et al. v. Actavis, Inc., et al.*, C.A. No. 12-366-RGA-CJB (D. Del.

dismissed Apr. 29, 2014) (the "First Litigation"). In that action, Novartis produced four million pages of documents. Accordingly, pursuant to Fed. R. Civ. P. 26(f)(3)(B), in the interest of avoiding cumulative and duplicative discovery, unnecessary costs, and to ensure that fact discovery can be completed within the aggressive seven month schedule that Mylan has proposed, Novartis has proposed limited rolling discovery, whereby discovery of paper and electronic documents under Fed. R. Civ. P. 34 shall be limited as set forth below unless otherwise agreed to by the parties or upon a particularized showing by the requesting party that such additional discovery relates to unique issues of fact or defenses that are non-cumulative of discovery that the producing party has already provided. Conducting a large-scale collection of ESI from multiple custodians and non-custodial data sources is not only unnecessary in this case in view of the First Litigation, but impractical given the short time frame in which the parties need to complete fact discovery in order to complete this case within the 30-month stay.

(i) "**Novartis's First Production**": On or before March 31, 2015, Novartis shall produce the patents-in-suit and associated prosecution histories; Investigational New Drug Application ("IND") No. 58,544; and New Drug Application ("NDA") No. 21-882;

(ii) "**Mylan's First Production**": On or before March 31, 2015, Mylan shall produce Abbreviated New Drug Application ("ANDA") No. 206585, including any correspondence with the FDA concerning ANDA No. 206585. Mylan shall also produce any agreements for an entity other than Mylan to manufacture, sell, or offer to sell the product described in ANDA No. 206585 upon approval;

(iii) "**Novartis's Second Production**": To the extent permitted by any applicable protective order or local law, and to the extent such documents remain within Novartis's possession, custody or control, on or before April 8, 2015, Novartis shall produce the following litigation documents filed or served by Novartis in the First Litigation: Novartis's submissions to the Court (including pleadings, letters, motions, briefs, declarations and exhibits); Novartis's responses to written discovery requests concerning issues other than infringement of the patents-in-suit; expert reports (and exhibits) served by Novartis concerning validity of the patents-in-suit, and transcripts of depositions (with exhibits, signature pages and any errata sheet(s)) of Novartis's fact and expert witnesses in the First Litigation. To the extent that Novartis cannot produce any such document described herein because it was designated by Defendants under the applicable protective order as containing confidential information, Novartis shall produce on April 8, 2015, a log identifying such documents so that Mylan may seek consent from Defendants regarding whether such documents may be produced in this action;

(iv) "**Novartis's Third Production**": To the extent permitted by any applicable protective order or local law, and to the extent such

documents remain within Novartis's possession, custody or control, on or before April 15, 2015, Novartis shall produce the following litigation documents filed or served by Defendants in the First Litigation: Defendants' submissions to the Court (including pleadings, letters, motions, briefs, declarations and exhibits); Defendants' responses to written discovery requests concerning issues other than infringement of the patents-in-suit; expert reports (and exhibits) served by Defendants concerning validity of the patents-in-suit, and transcripts of depositions (with exhibits, signature pages and any errata sheet(s)) of Defendants' expert witnesses in the First Litigation. To the extent that Novartis cannot produce any such document described herein because it was designated by Defendants under the applicable protective order as containing confidential information, Novartis shall produce on April 15, 2015, a log identifying such documents so that Mylan may seek consent from Defendants regarding whether such documents may be produced in this action;

(v) "**Novartis's Fourth Production**": To the extent permitted by any applicable protective order or local law, and to the extent such documents remain within Novartis's possession, custody or control, on or July 31, 2015, Novartis shall produce all non-privileged documents that Novartis produced in response to requests for production served pursuant to Fed. R. Civ. P. 34 in the First Litigation, including supplemental documents sufficient to show (1) sales and revenues of EXJADE®, and (2) marketing and promotional EXJADE® materials provided to healthcare providers that Novartis has generated since the end of the First Litigation; and

(vi) "**Mylan's Second Production**": On or before July 31, 2015, to the extent not otherwise produced as part of Mylan's First Production, Mylan shall produce: (1) any and all ANDAs submitted by Mylan seeking approval to market a generic version of EXJADE® (deferasirox) tablets, for oral suspension ("EXJADE® ANDA"); (2) any and all certifications or statements under 21 U.S.C. § 355(j)(2)(A)(vii) & (viii) prepared or submitted in connection with an EXJADE® ANDA, including related correspondence; (3) any and all documents submitted to the FDA in support of each EXJADE® ANDA, certification, or statement; (4) any and all studies or testing conducted during development of any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension, regardless of whether such studies and testing were submitted to the FDA; (5) any and all projections of approval or timelines for selling any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension; (6) any and all projections of sales and revenues for any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension; and (7) any and all documents that Mylan intends to support its claims or defenses.

(b) [**Mylan's Position**: Discovery will be needed on the issue of whether or not one or more claims of Novartis's U.S. Patent No. 6,465,504 (the "'504 patent") is invalid. Discovery will be needed on the issue of whether or not one or more claims of Novartis's U.S. Patent No. 6,596,750 (the "'750 Patent") is invalid. Discovery will also be needed on the issue of whether or not the product described in Mylan's Abbreviated New Drug Application ("ANDA") No. 206585 infringes one or more claims of the '504 patent or '750 patent literally or under the doctrine of equivalents. Discovery need not be conducted in phases or be limited or focused to a particular issue, other than what the proposed schedule provides. Mylan has already served its first set of requests for documents and things and submits that it has no way of knowing what documents were produced or what discovery was sought in the prior litigation. Thus the most practicable way of obtaining documents is through requests under Fed. R. Civ. P. 34. There would be no additional burden on plaintiffs if the prior litigation documents contain all relevant materials sought by Mylan]

(i) **Prior Litigation Documents**: To the extent permitted by any applicable protective order and local law, Plaintiff shall produce all litigation documents and discovery from *Novartis Pharm. Corp. v. Actavis, Inc.*, C.A. No. 12-366-RGA-CJB (D. Del.) (the "Prior Litigation") by March 15, 2015: (e.g. pleadings; discovery responses; expert reports; deposition transcripts and accompanying exhibits; pre-trial submissions and briefs, etc.). Novartis has already reviewed and identified relevant documents from the previous litigation and would be able to produce them in this case expeditiously. To the extent that Novartis contends any such document described herein is designated by Actavis under the applicable protective order as containing confidential information, Novartis shall produce on March 15, 2015, a log identifying such documents and further seek consent (as required under the protective order) from Actavis regarding whether such documents may be produced in this action. Unless Actavis moves for a protective order, Novartis shall further produce these documents within 30 days. Mylan has already served document requests on February 12, 2015 seeking the prior litigation documents identified herein.

(ii) **Mylan ANDA:** On or before March 15, 2015, Mylan shall produce Abbreviated New Drug Application ("ANDA") No. 206585, including any correspondence with the FDA concerning ANDA No. 206585. Mylan shall also produce any agreements for an entity other than Mylan to manufacture, sell, or offer to sell the product described in ANDA No. 206585 upon approval.

3. **Interrogatories**: Each side may serve a maximum of 25 interrogatories which shall be served in time to be completed prior to the close of fact discovery.

4. **Requests for Admission**: Each side may serve a maximum of fifty (50) requests for admission, excluding requests for admission relating to the authenticity of

documents, which shall be served in time to be completed prior to the close of fact discovery.

5. **Document Requests:** [**Novartis's Position**: Except as stated herein, there shall be no discovery requests under Fed. R. Civ. P. 34, unless otherwise agreed to by the parties or based on a showing of a particularized need that such additional discovery relates to unique issues of fact or defenses that are non-cumulative of discovery that the producing party has already provided]. [**Mylan's Position:** Mylan has already served its first set of requests for documents and things and submits that it has no way of knowing what documents were produced or what discovery was sought in the prior litigation. Thus the most practicable way of obtaining documents is through requests under Fed. R. Civ. P. 34. There would be no additional burden on plaintiffs if the prior litigation documents contain all relevant materials sought by Mylan].

6. **Fact Depositions:** [**Novartis's Position:** Each side may take a maximum of seventy (70) hours of deposition testimony. The parties shall make a good faith effort to avoid seeking cumulative or duplicative deposition testimony. In the absence of agreement among the parties or by order of the court, no deposition shall be scheduled prior to the completion of the document production described herein. Deposition testimony noticed under Fed. R. Civ. P. 30(b)(6) shall be limited to no more than ten (10) hours and is included within the 70-hour limit]. [**Mylan's Position**: Each side may take a maximum of seventy (70) hours of deposition testimony (not including expert witnesses and inventor depositions)].

7. **Service of Documents**: The parties have agreed that service by email shall be sufficient and that the three day rule shall not apply if service is made by email.

8. **Expert Discovery**:

(a) Expert reports on issues for which the parties have the burden of proof shall be due on October 19, 2015. [**Novartis's Position**: As invalidity is Mylan's burden, Mylan's opening expert report shall address all invalidity issues, including objective indicia of nonobviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079-80 (Fed. Cir. 2012) ("In sum, opinions of this court should not be read to require a burden-shifting framework in derogation of Stratoflex's directive that objective evidence be considered before making an obviousness determination and in disregard of where the burdens of proof and persuasion are properly placed in district court litigation."). Rebuttal expert reports shall be due December 3, 2015.]; [**Mylan's Position**: There should be three rounds of expert reports. As Plaintiffs have the burden on putting forth any objective indicia of nonobviousness, rebuttal expert reports (including plaintiffs' report(s) regarding any objective indicia of nonobviousness) shall be due November 19, 2015. Defendant's responsive expert reports regarding any objective indicia of nonobviousness shall be due December 21, 2015.]

(b) Each deposition of an expert witness shall be limited to seven (7) hours, except that if an expert is testifying on both validity and infringement, then the expert may be deposed for up to an additional seven (7) hours.

(c) Supplementations of expert reports under Rule 26(e) shall be limited to correcting inaccuracies or adding information that was not available at the time of the initial report and are due on or before twenty-one days (21) after service of rebuttal reports.

(d) To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion and filed on March 31, 2016.

9. **Claim Construction**: **[Novartis's Position**: Several terms in the claims of the patents-in-suit were construed in the First Litigation. Mylan has not identified any issue requiring construction in this action, despite having an obligation to set forth a "detailed statement of the factual and legal basis" for its challenge to Novartis's patents in its paragraph IV notice letter. To the extent that Mylan identifies a claim construction issue in its non-infringement or invalidity contentions that it failed to include in its "detailed statement," then the parties should meet and confer at that time to discuss whether claim construction is necessary and the schedule for such claim construction. Mylan's blanket request to tie up the Court's docket with a claim construction hearing and a schedule for claim construction briefing before having identified any issue requiring construction is premature.]; [**Mylan's Position**: Mylan has fully complied with all scheduling requirements and has set forth a "detailed statement of the factual and legal basis" for its challenge to Novartis's patents in its paragraph IV notice letter. Claim construction is a legal issue that is properly decided by the Court. Novartis first proposed adoption of the Magistrate's claim construction report from the prior litigation during the parties rule 26(f) meeting and Mylan informed Novartis that the ruling was not fully adopted by the District court and that Mylan has not had any opportunity to examine discovery from the prior litigation and believes that scheduling of Markman events is essential to evaluate whether there is any disagreement. Accordingly Mylan respectfully requests that the Court calendar Markman events as it is premature to decide the issue at this juncture, and if the parties are subsequently able to agree on the construction of all of the terms, then it can be taken off calendar. The parties will work in good faith to determine if the Magistrate's recommended findings from the prior litigation should be adopted in the current matter]

10. **Protective Order**: The parties have agreed that they will need a protective order addressing claims of privilege or protection as trial-preparation material asserted after production. A procedure applicable in the event that one of the parties wishes to assert a claim of privilege or protection after production will be included in a proposed protective order to be submitted to the Court shortly. By

March 4, 2015, the parties shall submit a joint proposed protective order to the Court.

11. **Dispositive Motions**: [**Novartis's Position**: The issues in this bench trial are not conducive to dispositive motions]. **[Mylan's Position**: Mylan believes that several issues in this case can be adjudged by dispositive motions and proposes a deadline of March 31, 2016 for such motions to be filed.].

12. **The First-Filed Case**: If the District of Delaware determines that it has personal jurisdiction over Mylan, Mylan and Novartis agree that the above discovery shall apply in the Delaware action and that the fact discovery dates above shall remain in effect.

13. **Schedule**: The parties have been unable to reach agreement regarding a proposed schedule.

Their respective proposals are as follows:

Event	Agreed Date	Novartis's Proposed Date	Mylan's Proposed Date
Parties Submit Joint Proposed Protective Order	March 4, 2015		
Initial Disclosures	March 12, 2015		
Deadline for amending pleadings		August 31, 2015	March 4, 2015
Deadline for joining parties		August 31, 2015	March 4, 2015
Fact discovery shall be commenced in time to be completed by	October 8, 2015		
Novartis Proposal On Production of Documents			
Novartis's First Production		March 31, 2015	March 15, 2015
Mylan's First Production		March 31, 2015	March 15, 2015
Novartis's Second Production		April 30, 2015	March 15, 2015
Novartis's Third Production		April 30, 2015	March 15, 2015
Novartis's Fourth Production		July 31, 2015	March 15, 2015
Mylan's Second Production		July 31, 2015	N/A
Mylan Proposal On Production of Documents			
Novartis shall produce all litigation documents and discovery from *Novartis Pharm. Corp. v. Actavis, Inc.*, C.A. No. 12-366-RGA-CJB (D. Del.) (the "Prior Litigation"): (e.g. pleadings; discovery responses; expert reports; deposition transcripts and accompanying exhibits; pre-trial submissions and briefs, etc.)		N/A	March 15, 2015

Event	Agreed Date	Novartis's Proposed Date	Mylan's Proposed Date
Novartis shall produce the patents-in-suit and associated prosecution histories; Investigational New Drug Application ("IND") No. 58,544; and New Drug Application ("NDA") No. 21-882		N/A	March 15, 2015
Defendants Produce ANDA		N/A	March 15, 2015
Expert Discovery			
Opening expert reports on issues for which the party bears the burden of proof	October 19, 2015		
Rebuttal expert reports		December 3, 2015	November 19, 2015
Defendant's responsive expert reports regarding any objective indicia of nonobviousness		N/A	December 21, 2015
Close of Expert Discovery	February 29, 2016		
Deadline for Dispositive Motions		N/A	March 31, 2016
Daubert Motions	March 31, 2016		
Responses to Daubert Motions	April 29, 2016		
Pre-trial conference	June 2016		
Trial	July 2016		
Markman Events		**Novartis Proposed Date**	**Mylan Proposed Date**
Parties identify claim terms for construction		TBD	April 21, 2015
Parties exchange proposed constructions, including initial identification of all intrinsic and extrinsic evidence to be relied upon		TBD	May 12, 2015
Parties file opening Markman briefs		TBD	June 8, 2015
Parties file responsive Markman briefs		TBD	June 22, 2015
Markman hearing		TBD	June 29, 2015
Markman ruling			Court's convenience

14. **Trial:** [**Novartis's Position**: Novartis submits that the issues can be tried in 28 hours, with the time being equally divided between Novartis and Mylan]. [**Mylan's Position:** Mylan submits that trial will take five (5) days].

15. **Magistrate Judge**: The parties do not consent to trial by a magistrate judge.

16. **Case Management**: Mylan believes it to be necessary for the Court to pre-schedule periodic telephonic status conferences in advance.

17. **Disputed Facts**: Other than the admissions contained in Mylan's answer and Novartis's reply to Mylan's Counterclaim, the parties are unable to agree upon disputed facts that have been alleged with particularity in the pleadings.

18. **Settlement, Early Mediation, and ADR**: The parties have not yet discussed the prospects for settlement, and settlement at this time is unlikely. As the case develops, the parties will voluntarily discuss settlement by mutual agreement to the extent circumstances change.

19. **Agenda for Scheduling Conference**: The parties assert that no motions are pending and that the proposed schedule set forth in this Report should be discussed at the scheduling conference.

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